IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

WARDELL FLEMING,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 2:15-CV-02799-JPM
	)	
JANSSEN PHARMACEUTICALS, INC. ET. AL.,	)	
	)	
Defendants.	)	

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COMPLAINT UNDER F.R.C.P. 12(B)(2) AND 12(B)(6)

This product liability action arises from Defendants' design, manufacture, and marketing of the prescription drug Invokana®. Invokana is a prescription drug, known as a sodium-glucose cotransporter 2 inhibitor, primarily used for the treatment of type 2 diabetes. Invokana inhibits the body's ability to absorb glucose, causing it to be excreted by the kidneys in a population of patients known to be at risk for kidney disease. As a direct and proximate result of taking Invokana, Plaintiff Wardell Fleming suffered kidney failure. Plaintiff seeks compensatory damages, attorneys' fees, and punitive damage to recover his losses.

The Complaint states a claim for relief under each theory of liability asserted, with respect to each Defendant. Nevertheless, Defendants Johnson & Johnson and Janssen seek dismissal of all or part of Plaintiff's claims on four grounds: (1) the Court lacks jurisdiction over Johnson & Johnson; (2) the Court should broaden the Supreme Court's ruling in *Mutual Pharmaceutical Company v. Bartlett*, 133 S. Ct. 2466 (2013), to find that design defect claims against brand name drug manufacturers are preempted by federal law; (3) that Plaintiff's

damages are not recoverable under the Tennessee Consumer Protection Act (TCPA); and (4) the Complaint fails to state a claim under Rule 12(b)(6). Each of these arguments is without merit.

First, Johnson & Johnson clearly is subject to personal jurisdiction in Tennessee, as it designed and developed Invokana; earned hundreds of millions (and likely over a billion) dollars on sales of Invokana in the U.S., including Tennessee; marketed and sold Invokana, with Janssen, in Tennessee; and caused injury to Plaintiff in Tennessee. Second, Defendants' preemption argument should be rejected out of hand as it amounts to an attempt to foreclose *all* design defect claims. Defendants would make the FDA the *de facto* judge and jury with respect to drug safety, leaving Courts with no power and consumers with no remedy. Third, Plaintiff's damages as alleged are recoverable under the TCPA. Fourth, the Complaint states a claim for relief pursuant to each theory of liability asserted. Defendants seek dismissal in large part by repeating catchphrases and concepts from *Twombly* and *Iqbal* (conclusory, formulaic, etc.) and then asserting that the Complaint does not meet the *Twombly*/*Iqbal* standard.

ARGUMENT

A. This Court Has Personal Jurisdiction Over Defendant Johnson & Johnson.

Johnson & Johnson's conduct in developing, designing, and selling Invokana in Tenessee subjects it to personal jurisdiction here. Specific jurisdiction refers to jurisdiction over a defendant in a suit "arising out of or related to the defendant's contacts with the forum." *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984). "The inquiry whether a forum State may assert specific jurisdiction over a nonresident defendant focuses on the relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014) (internal quotations omitted). As this Court is sitting in diversity, the exercise of personal jurisdiction is defined by the Tennessee long-arm statute. *Payne v. Motorists' Mut.*

Ins. Companies, 4 F.3d 452,455 (6th Cir. 1993).[1] "The jurisdictional limits of Tennessee law and of federal constitutional due process are identical." *Id.*

The Due Process Clause bases the exercise of personal jurisdiction on whether the defendant has "minimum contacts" with the forum state "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). A state has a "manifest interest" in providing its residents with a convenient forum for "redressing injuries inflicted by out-of-state actors," particularly where the defendant "purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 473 & 475 (1985). This may be satisfied by deliberately placing a product into the stream of commerce with the knowledge and intent that it be sold in the forum. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 298 (1980).

To defeat a motion to dismiss for lack of personal jurisdiction, "plaintiffs need only make a prima facie showing of jurisdiction." *Beydoun v. Wataniya Restaurants Holding, Q.S.C.*, 768 F.3d 499, 504 (6th Cir. 2014). Further, the court "will construe the facts in the light most favorable to the nonmoving party." *Id.* When determining whether a foreign defendant's contacts are sufficient to establish specific jurisdiction, courts will consider the defendants contacts at the national level, as well as contacts in the venue state, including the quantity, nature and quality of sales made by the defendant in the venue state. *See e.g. State v. NC Sumatra Tobacco Trading Co.*, 403 S.W.3d 726, 762 (Tenn. 2013) (declining to find jurisdiction where the foreign defendant did not engage in aggressive national marketing and had only shipped 1,159 cases of cigarettes to Tennessee).

[1] Plaintiff does not claim that Johnson & Johnson is subject to general jurisdiction in Tennessee, but instead asserts specific jurisdiction.

The Complaint sufficiently establishes jurisdiction. Plaintiff alleges that "Johnson & Johnson designed and developed" Invokana in collaboration with Mitsubishi Tanabe. *Compl.* at ¶ 18. Johnson & Johnson's subsidiary, Janssen, then acquired the rights to market and sell Invokana to patients in Tennesse and other U.S. markets. *Id.* at ¶ 19. Defendants, whether directly or through their agents, collectively researched, developed, designed, licensed, manufactured, marketed, distributed, and sold Invokana in Tennessee with a reasonable expectation that Invokana would be used in Tennessee. *Id.* at ¶¶ 9, 12. Defendants, directly or through their agents, conducted nationwide sales and marketing campaigns, including in Tennessee, to promote Invokana. *Id.*at ¶ 34. And they disseminated false and misleading information about Invokana to health care professionals in Tennessee with the expectation that such information be used and relied on in Tennessee. *Id.* at ¶ 13. As a result of these acts, Plaintiff was prescribed Invokana in Tennessee, ingested Invokana in Tennessee, and suffered severe injury in Tennessee. *Id.* at ¶¶ 15, 35–36, 40, 45.

Plaintiff further alleges Johnson & Johnson transacted and solicited a significant amount of business in Tennessee through its agents and representatives, and derived a substantial amount of revenue from Tennessee. *Id.* at ¶¶ 12, 14, 20. The total sales of Invokana were so robust that Johnson & Johnson reported $278 million in earnings from Invokana in the first quarter of 2015, which necessarily includes significant sales in Tennessee. *Id.* at ¶ 20. If sales continue apace, Johnson & Johnson will have earned over ***$1 billion*** on Invokana in 2015- and Invokana has only been on the U.S. market since April of 2013.[2]

[2] Invokana sales are likely to far exceed this number, as Johnson & Johnson earned ***$890 million*** on U.S. sales of Invokana in the first 9 months of 2015. *See* Johnson & Johnson Third Quarter 2015 Sales of Key Prods. at 2, *available at* http://files.shareholder.com/downloads/JNJ/1188176531x0x854183/3152FFAB-82A7-4F38-AA75-D25F107767DB/Sales_of_Key_Products_Franchises_3Q2015.pdf.

In summary, Plaintiff alleges that Johnson & Johnson designed Invokana. Johnson & Johnson, along with its subsidiary, placed Invokana in the stream of commerce, marketed Invokana in Tennessee, sold Invokana in Tennessee, derived substantial revenue from sales of Invokana in Tennessee, and injured Plaintiff in Tennessee. There can be no question of the Court's jurisdiction. *Daimler AG v. Bauman*, 134 S. Ct. 746, 759 n.13 (2014) ("corporation can purposefully avail itself of a forum by directing its agents or distributors to take action there"); *Asahi Metal Indus. v. Superior Court of Cal.*, 480 U.S. 102, 112 (1987) ("designing the product for the market in the forum State" or "marketing [a] product through a distributor" each can constitute purposeful availment).

Despite this, Johnson & Johnson attempts to hide behind its subsidiary, claiming to be a holding company. *Defs. Mem.* at 2, 3. Plaintiff's allegations contradict Johnson & Johnson's position. *Compare Compl.* at ¶ 18 (alleging Johnson & Johnson "designed and developed" Invokana in collaboration with Mitsubishi Tanabe), *with Defs. Mem.* at 2, 3, 6 (claiming Johnson & Johnson did not manufacture, market or sell Invokana, but failing to address its role in design or development). Factual disputes must be resolved in Plaintiff's favor. *See Caboodles Cosmetics, Ltd. Partnership v. Caboodles, LLC*, 412 F. Supp. 2d 872, 877 (W.D. Tenn. 2006) (Donald, J.). Moreover, this same defense was recently rejected in the Pinnacle Hip Implant MDL, and should be so rejected here. *In re DePuy Orthopaedics, Inc.*, MDL No. 2244, 2014 WL 3567593, *1-2 (N.D. Tex. July 18, 2014) (rejecting argument and finding personal jurisdiction over Johnson & Johnson).[3] Johnson & Johnson developed Invokana with the intent that it be sold in Tennessee, derived substantial revenue from the sale of Invokana in Tennessee, and, with its

[3] Defendants' cited authority on this issue, *Androphy v. Smith & Nephew, Inc.*, 31 F. Supp. 2d 620 (N.D. Ill. 1998), is outdated as it was decided eighteen years ago. Moreover, in *Androphy* the plaintiff made no allegations against Johnson & Johnson. Therefore it also is distinguishable. *Id.* at 622.

subsidiary, marketed and sold Invokana in Tennessee. Accordingly, Johnson & Johnson is subject to personal jurisdiction in Tennessee.[4]

B. Plaintiff's Design Defect Claims Are Not Preempted.

Next, Defendants try to shoehorn this case, which involves a brand-name drug, into the Supreme Court generic drug preemption decision, *Mutual Pharmaceutical Company v. Bartlett*, 133 S. Ct. 2466 (2013), arguing that all design defect claims are preempted as a matter of law. In essence, Defendants argue they should be able to develop, market, and sell a drug — even if they know it is unreasonably dangerous — until the FDA affirmatively steps in to stop them, and even then they should bear no financial responsibility for the damage caused. Thus, Defendants posit that the FDA should serve as *de facto* judge and jury, leaving Courts without power and consumers without remedy. Such a premise should be rejected out of hand.

In *Bartlett*, the Supreme Court held that certain design defect claims brought against manufacturers of ***generic*** drugs are preempted, because the Federal Food, Drug, and Cosmetic Act ("FDCA") requires a generic drug to have the same design and labeling as its brand name equivalent. *Id.* at 2471. Therefore it is "not possible" for a generic manufacturer to redesign its product or strengthen its warning without violating federal law. *Id.* at 2475. Because "federal law forbids an action that state law requires," state law was preempted with respect to generic drug manufacturers. *Id.* at 2476–77.

In making this holding, *Bartlett* did not overturn its previous holding in *Wyeth v. Levine*, 555 U.S. 555 (2009), which examined whether the FDCA preempted state law claims for failure to warn involving a brand-name drug. In holding there was no such preemption, the Court observed that Congress declined to preempt state tort law when enacting the FDCA or at any

[4] In the alternative, to the extent the Court finds Plaintiff's allegations insufficient, Plaintiff requests the opportunity to take discovery to further develop jurisdictional facts. *See*, Section E, *infra.*

time in the FDCA's 70-year history. *Wyeth*, 555 U.S. at 574. "[Congress'] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. Despite this clear statement, Defendants ask this Court to hold that all design defect claims are preempted by federal law.

Defendants support this outlandish argument by honing in on a single sentence in *Bartlett* — a case that specifically only addressed generic drugs — and attempting to use that sentence to undermine all private causes of action against pharmaceutical companies. However, *Bartlett* preemption simply does not apply to brand-name drugs because the FDCA's "sameness" requirement is not implicated. Not surprisingly, Defendants' argument has been rejected by a number of Courts throughout the country. *See, e.g.*, *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.*, 2015 WL 7075916, *18–24 (E.D. Pa. Nov. 13, 2015) (design defect claims against brand-name drug manufacturers not preempted by federal law); *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014) (holding same); *Frazier v. Mylan, Inc.*, 911 F. Supp. 2d 1285, 1295 (N.D. Ga. 2012) (rejecting pre-emption defense because defendant "pointed to no federal requirement mandating that [its] product be designed in a certain way or asserted that the FDA requires a certain design").[5] *See also, Dopson-Trout v. Novartis Pharm. Corp.*, 975 F. Supp. 2d 1209, 1215–18 (M.D. Fla. 2013) (rejecting preemption argument on failure to warn claim involving a brand-name drug).

In *Estate of Cassel v. ALZA Corp.*, 2014 WL 856023, the Western District of Wisconsin was presented with a similar factual situation and argument as is at issue here. *Id.* at *1. After distinguishing *Bartlett* because the defendants did not sell generic drugs, *id.* at *4-5, the court

[5] Even though *Frazier* was decided before the Supreme Court's decision in *Bartlett*, the analysis is still valid because "there is no pronouncement in *Bartlett* that conflicts with the reasoning in *Frazier*." *Estate of Cassel v. ALZA Corp.*, No. 12-771, 2014 WL 5330463, *16 n.6 (W.D. Wis. Mar. 5, 2014).

found the circumstances also were factually dissimilar because the plaintiffs' claims were based on the defendants' "duty to employ an alternative design … from the beginning, *before* FDA approval." *Id.* at *5. As no federal law prohibited the defendants from employing a reasonably safe alternate design, the claims were not preempted. *Id.* at *5- 6. Any other interpretation "would effectively foreclose all design-defect claims against drug manufacturers." *Id.* at *5. *Accord Sullivan v. Aventis, Inc.*, 2015 WL 487912, *6 (S.D.N.Y. Aug. 12, 2015) (no federal law "restricts a brand-name drug manufacturer from designing a reasonably safe product prior to FDA approval"); *Acree v. Watson Pharm.*, 2012 WL 5306296, *6 (N.D. Ill. Oct. 26, 2012) (holding same).

Here, Plaintiff began taking Invokana within months of Invokana's FDA approval. *Compl.* at ¶¶ 21, 35. Thus, like in *Cassel*, the main focus of Plaintiff's claims is on the original design of Invokana before FDA approval, not Defendants' failure to redesign the drug after FDA approval.[6] And no federal law prevented Defendants from complying with their duty to design a reasonably safe drug. But regardless of the basis of Plaintiff's claims — whether it be in Defendants' initial defective design, or in their failure to redesign Invokana — the result is the same. Defendants are brand name drug manufacturers and therefore the "sameness" requirement does not apply to them. It is not impossible for Defendants to redesign Invokana, nor was it impossible for them to design it properly in the first place. Plaintiff's claims are not preempted.

The Court should reject Defendants' attempt to extend *Bartlett* and should recognize that even *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281 (6th Cir. 2015) does not support Defendants' position and is distinguishable from the instant case. In *Yates*, the court rejected the

[6] Defendants cobble together isolated words from different paragraphs of the Complaint in an attempt to show that Plaintiff's argument focuses solely on the duty to redesign Invokana. This ignores the vast majority of Plaintiff's allegations. *Compare Defs. Mem.* at 19-20, *with Compl.* at ¶¶ 53–59. If Plaintiff were so inclined, he could undertake a similar exercise with Defendants' arguments: "Plaintiff's claims" "are not preempted" "and should" "not be" "dismiss[ed]." *Defs. Mem.* at 2, 11, 17.

premise that all design defect claims are preempted as a matter of law. *Id.* at 294. Instead, the court examined the facts at the summary judgment stage to determine whether compliance with federal law was impossible under those particular circumstances. *Id.* at 297-300. Moreover, the Court reaffirmed its holding in *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010), which examined the "duty to exercise reasonable care" in designing a drug prior to FDA approval and found no preemption. *Yates*, 808 F.3d at 300.[7] Defendants' remaining authority completely fails to address the duty to initially design a reasonably safe product. *See Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 771-72 (S.D. Ohio 2015); *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 875 (N.D. Ohio 2014).

If Defendant's prevail, it would serve to render drug companies completely immune from suit once they obtain FDA approval, regardless of the harm wrought on consumers. This is contrary to the intent of the FDCA and Supreme Court precedent. *See Wyeth*, 555 U.S. at 579 (finding state tort law compliments the FDA's work by "uncover[ing] unknown drug hazards and provid[ing] incentives for drug manufacturers to disclose safety risks promptly"). *Accord Cassel*, 2014 WL 856023, *5.

Defendants devote a significant amount of time explaining why it is impossible to redesign Invokana. This is largely irrelevant, as the argument rests on a faulty interpretation of impossibility preemption and ignores the fact that Plaintiff's claims focus on the initial design of Invokana prior to FDA approval. Should the Court nevertheless choose to consider the argument, it is premature. While Defendants suggest an impossibility preemption analysis can occur at the

[7] The *Yates* court found that *Wimbush's* rationale did not apply in the circumstances before it because the drug had been on the market for 4 years before the plaintiff started taking the drug, making the argument too attenuated. *Yates*, 808 F.3d at 300. As set forth above, the Court should reject *Yates.* But even if the Court were to find *Yates'* rationale persuasive, it does not apply here. The *Yates* court contrasted the facts before it with the situation in *Wimbush*, in which the drug was only on the market for little over a year. *Id*. Here, the Plaintiff's situation is much more like that in *Wimbush*. Invokana was only on the market for 8 months before Plaintiff began taking the drug, and the FDA has received an alarming number of reports of severe kidney damage in the short period of time that Invokana has been on the market. *Compl.* at ¶¶ 21, 26–27.

motion to dismiss stage, they rely largely on clear-cut cases that involved generic drugs (*PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)), or where there is "clear evidence the FDA would not have approved a change. . ." (*Rheinfrank*, 119 F. Supp. 3d at 766)). Defendants' other authority — *Yates, Rheinfrank, Booker* and *Shah v. Forest Labs Inc., 2015 WL 3396813*— addressed this fact-specific issue at the summary judgment stage, after discovery. Should the Court choose to entertain this argument, any analysis should occur after discovery so that the issues can be fully developed. *See* Section E, *infra.*

"Impossibility pre-emption is a demanding defense," on which the Defendants bear the burden of proof. *Wyeth*, 555 U.S. at 572. Defendants have not met that burden.

C. Plaintiff's Damages are recoverable under the TCPA

To recover under the TCPA, the plaintiff must allege and eventually prove that the defendant engaged in an unfair act or practice declared unlawful by the TCPA, and that the defendants' conduct caused an "ascertainable loss of money or property, real, personal, or mixed, or any article, commodity, or thing of value wherever situated . . . ." *Tucker v. Sierra*, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005) (citing Tenn. Code Ann. § 47-18-109(a)(1). "[T]he TCPA is explicitly remedial, and Tennessee courts are therefore required to construe it liberally to protect consumers in Tennessee and elsewhere." *Id.*

Here, Plaintiff alleges that Defendants violated the TCPA, that he suffered damages as a result of Defendants' violation(s), and Plaintiff requested that this Court award economic damages. *Compl.* ¶¶ 224-227, prayer for relief. As the end purchaser of Invokana, Plaintiff's economic damages stem from the purchase price of the drug that he would not have purchased but for Defendants' wrongful conduct. *Id.* at ¶ 89, 200. Plaintiff's economic damages are separate and distinct from Plaintiff's damages which flow from the personal injury he suffered

Thus, Plaintiff has pled damages which are recoverable under the TCPA. *See Riddle v. Lowe's Home Centers*, 802 F. Supp. 2d 900, 909 (M.D. Tenn. 2011).

D. The Complaint Pleads Plausible Claims For Relief Sufficient To Satisfy Federal Pleading Standards.

When ruling on a 12(b)(6) motion to dismiss, the "court should construe the complaint in the light most favorable to the plaintiff[.]" *Caboodles, LLC*, 412 F. Supp. 2d at 877. All factual allegations must be taken as true, and all inferences must be drawn in favor of the Plaintiff. *Id.* A complaint survives dismissal so long as it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint provide "a short and plain statement of the claim showing the pleader is entitled to relief" and "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. *See also Iqbal*, 556 U.S. 662. The plaintiff need not plead particularized facts, but the factual allegations in the complaint must be enough to raise a right to relief above the speculative level. *Twombly*, 550 U.S. at 555. A claim is plausible on its face when the plaintiff pleads factual content that allows the court to draw a reasonable inference that the defendant is liable for the alleged misconduct. *Iqbal*, 566 U.S. at 662.

Twombly did not overturn the well-established practice of notice pleading in federal court. *See Twombly*, 550 U.S. at 570. Nor did *Twombly* require a plaintiff to state enough facts to show it is likely to prevail on its claims. Rather, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is impossible and 'that a recovery is very remote and unlikely.'" *Id.* at 556. *Twombly* "simply calls for enough facts to

raise a reasonable expectation that discovery will reveal evidence of [the claim or element].” *Id.* Under this standard, a complaint survives a motion to dismiss if it “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Iqbal*, 556 U.S at 663. Moreover, the plaintiff is entitled to the “benefit of imagination.” *Twombly*, 550 U.S. at 563. Rule 8(e) provides that “[p]leadings must be construed so as to do justice.” When deciding on a motion to dismiss, the court should draw on its judicial experience and common sense. *Maness v. Boston Scientific*, 751 F. Supp. 2d 962, 966 (E.D. Tenn. 2010) (quoting *Iqbal*, 129 S. Ct. at 1950).

1. Design Defect Claims

Plaintiff properly stated a claim for strict liability design defect (Count I) and negligent design (Count IX). Under the Tennessee Product Liability Act (TPLA), at the motion to dismiss stage, the pleadings must merely allege facts which allow the court to infer that (1) a product was defective or unreasonably dangerous; (2) that the defect existed at the time the product left the manufacturer’s control; and (3) that the plaintiff’s injury was caused by the defective product. *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008). The TPLA defines a defective condition as “a condition of a product that renders it unsafe for normal or anticipatable handling and consumption.” Tenn. Code Ann. § 29-28-102(2). The TPLA defines unreasonably dangerous as “dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics . . . .” *Id.* § 29-28-102(8). Under the TPLA, courts will utilize either the “consumer expectation test” or the “prudent-manufacturer test” to determine whether a product is unreasonably dangerous. *Tilden v. General Elec. Co.*, 2012 WL 1023617, at *3. “If an action is based on express warranty or misrepresentation claims, it is not necessary to prove that the

product was defective or unreasonably dangerous. *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 967 (M.D. Tenn. 2002) (citing Tenn. Code Ann. § 29-28-105(c)).

The allegations in the Complaint state a plausible claim for relief and, despite Defendants' generalized protestations to the contrary, are not merely formulaic recitations of elements. The Complaint alleges Defendants designed Invokana in a condition that rendered it unreasonably dangerous in a variety of respects (*Compl.* at ¶ 54), including, *inter alia*, that Invokana's design causes excess glucose to be excreted by the kidneys in a population of patients known to be at risk for kidney disease (*id.* at ¶ 24), the FDA recently issued a health advisory regarding Invokana and ketoacidosis, and subsequently required Defendants to change the label of Invokana to warn of ketoacidosis, which can cause organ failure; and serious urinary tract infections, which can lead to kidney infection and kidney failure (*id.* at ¶¶ 27, 31). Furthermore, Plaintiff alleged the use of Invokana was more dangerous than other risks associated with the treatment of diabetes (*id.* at ¶ 54(b)), the benefits of Invokana were outweighed by the risks (*id.* at ¶ 63), there are other design alternatives, that have a better safety profile (*id.* at ¶ 64), and there were safer alternative diabetes medications that do not carry the risk of Invokana (*id.* at ¶¶ 32, 54(d), 54). With respect to the consumer expectation test, Plaintiff alleged the product was more dangerous than the expectations of ordinary consumers, Plaintiff, and prescribing physicians. *Id.* at ¶¶ 47, 54(b), 62, 63.

And with respect to the prudent-manufacturer test, Plaintiff alleged that other diabetes medications have lower risk than Invokana and are equally effective. *Id.* at ¶¶ 54(d), 64. Had Plaintiff and his healthcare provider known of the risks and dangers associated with Invokana, he would not have been prescribed or used the drug. *Id.* at ¶¶ 45, 200. And as a direct, foreseeable,

and proximate result of Defendants' defective design of Invokana, Plaintiff was injured. *Id.* at ¶ 70. These allegations adequately state a claim. [8]

2. Failure to Warn

Next, Defendants' challenge Plaintiff's failure to warn claim (Count II). Defendants erroneously assert that because Invokana's label mentioned the risk of kidney injury, Plaintiff cannot state a claim as a matter of law. Simply because the Invokana label mentioned the type of injury Plaintiff ultimately suffered does not mean Defendants fulfilled their duty to warn. Rather, the warning must be ***adequate***.[9] "The adequacy of a drug manufacturer's warnings is normally a question of fact." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994). Defendants also erroneously claim that Plaintiff did not adequately allege how the warnings were defective or how the defect caused Plaintiff's injuries.

A determination of the adequacy of a warning most definitely involves determining whether the drug warns of the severity of the risks associated with use. For instance in *D.W.K. v. Abbott Labs., Inc. (In re Depakote)*, 2015 WL 4776093 (S.D. Ill. Feb. 14, 2015), the Court denied summary judgment on a failure to warn claim where the drug contained a black box

[8] Defendants' reliance on *Maness v. Boston Scientific*, 751 F. Supp. 2d 962 (E.D. Tenn. 2010) is misplaced. In *Maness*, the plaintiff failed to allege facts that would allow the court to infer the device was unreasonably dangerous, and instead, merely alleged the defendants failed to warn others of the dangerous propensities of the device. *Id.* at 970. Contrary to Defendants' assertion that Plaintiff failed to allege any facts sufficient to permit this Court to infer that Invokana is unreasonably dangerous, Plaintiff alleged that the design of the drug, permitting excess glucose to be excreted through the kidneys of diabetes patients, is unreasonably dangerous (*Compl.* at ¶ 2), and further pointed out that the FDA has recently acted, twice, in an effort to make the public aware of the dangers associated with Invokana. *Id.* at ¶¶ 27, 31.

Similarly, Defendants' reliance on *McElroy v. Amylin Pharms., Inc.*, 573 Fed. Appx. 545 (6th Cir. 2014) is misplaced. In *McElroy*, the plaintiff alleged he "possibly" had pancreatitis, a condition the FDA had recently alerted, and pancreatic panniculitus, which as that court notes "are simply different." *Id.* at 546. Here, Plaintiff alleged kidney failure, kidney damage reduced kidney function and he pointed to action from the FDA alerting to dangers that can directly lead to kidney failure, kidney damage and reduced kidney function. *Compl.* at ¶¶ 40,48.

[9] Without citing support, Defendants seek to improperly introduce labeling information claimed to be in effect at the "relevant" time. *Defs. Mem.* at 14. The labeling information that is actually applicable to this case is a factual issue that is not properly decided at the motion to dismiss stage. Plaintiff's allegations are to be taken as true. *Caboodles, LLC*, 412 F. Supp. 2d at 877.

warning regarding the injury, but allegedly failed to warn of the severity or magnitude of the risk. *Id.* at *4-9. In ruling, the Court reasoned: "In order to determine whether or not the warnings are adequate, the Court must look to whether the warnings are sufficient in form, content, and intensity. The adequacy of the warning is measured not only by what is stated, but also by the manner in which it is stated." *Id.* at *4 (internal citation and quotation omitted). *Accord*, *Sellers v. Boehringer Ingelheim Pharm., Inc.*, 881 F. Supp. 2d 992, 1004–05 (S.D. Ill. July 25, 2012) (denying motion to dismiss in Pradaxa MDL, in which the label warned of the risk of a bleeding event but not the extent of the risk); *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 771 (S.D. Ohio 2015) ("the Court is not persuaded that the mere fact that the label listed Depakote as a Pregnancy Category D drug and included a Black Box warning indicates that the label was adequate as a matter of law. Rather, there is a question of fact as to whether the 2003 Depakote warning was adequate.") Warnings are considered adequate only when they contain "full and complete disclosure of the potential adverse reactions to the drug." *Pittman*, 890 S.W.2d at 429.

Contrary to Defendants assertion, the Complaint adequately alleges how the warnings provided were defective and how they caused Plaintiff's injury. *See, e.g.*, *Compl.* at ¶¶ 75, 83–86 (knowledge and failure to warn); *id.* at ¶ 85–88 (inadequate warning); and *id.* at ¶¶ 76–78, 89, 91 (proximate cause). As such, the Complaint states a claim for failure to warn.

3. Negligence Claims, Breach of Warranty and Fraud Claims

Defendants' assert that Counts I-XI should be dismissed for failure to meet pleading standards. Defendants argue specifically only about Plaintiff's design defect (Count I & Count IX) and failure to warn (Count II) claims, while remaining silent as to the rest of Plaintiff's allegations. Accordingly, to the extent that Plaintiff's remaining allegations rely on establishing a

design defect or failure to warn, Plaintiff has already addressed the merits of Defendants argument in the foregoing discussion. *See,* Section D1, D2, supra.

Presumably, Defendants cite *Maness* and *Tilden* in support of dismissal of the remaining allegations. Nevertheless, Defendants reliance on *Maness* and *Tilden* is misplaced. *See*, n.8, *supra* (distinguishing *Maness* from the instant case). Like *Maness*, the *Tilden* plaintiff made vastly different allegations than those made here. In *Tilden*, the plaintiff merely alleged use of the device, and injury. *Tilden,* 2012 WL 1023617, at *5. Here, the Complaint alleges not only use of Invokana, but also factual allegations which permit this Court to infer that Invokana is unreasonably dangerous, and that the unreasonably dangerous condition of Invokana caused Plaintiff's injuries. Merely citing *Maness* and *Tilden* does nothing to cast doubt on the pleading sufficiency of Counts I- XI. Accordingly, Defendants' argument is without merit.

E. Request for Limited Discovery.

To the extent this Court chooses to entertain the jurisdictional and preemption arguments proposed by Defendants, Plaintiff respectfully requests leave to conduct limited discovery. "A district court has discretion whether to hold in abeyance a decision on a motion to dismiss for lack of personal jurisdiction to enable the party to conduct discovery." 5A *Federal Prac. & Proc.* § 1351. And while Plaintiff disputes the legal rationale of *Yates*, 808 F.3d 281 (6th Cir. 2015), Defendants' own authority recognizes that the potential application of the preemption doctrine to brand name drugs turns on the facts, which therefore necessitates discovery. *Id.* at 293–300.

If the Court finds that Plaintiff has not sufficiently established that Johnson & Johnson targeted Tennessee, Plaintiff should be able to take discovery to develop facts that relate to: Johnson & Johnson's contacts with Tennessee; its targeting of markets in Tennessee; its involvement in the development, marketing and sale of Invokana; it agreements with Janssen, Mitsubishi Tanabe, and related companies regarding Invokana; and Defendants' corporate

structure. This discovery is warranted because the details of the process and agreements by which Invokana came to Tennessee is not known at this time. Discovery is necessary for Plaintiff to determine what role Johnson & Johnson played in the development of Invokana, and the extent to which its role included contacts with Tennessee. In addition, discovery is necessary to uncover the arrangements between Johnson & Johnson, Janssen, and Mitsubishi Tanabe regarding who would carry out which tasks with respect to designing, developing, testing, marketing, and selling the product. And should the Court decide to entertain Defendants' faulty preemption argument, Plaintiff should be able to take limited discovery into the science underlying Invokana itself — its design, development, and production — how it works, and how (or if) it can be made more safe. Only limited information about Defendants' operations with regard to Invokana or about the design, development, and production of Invokana are publicly available.

If permitted to conduct discovery, Plaintiff would seek, at a minimum, Corporate Representative depositions pursuant to Federal Rule of Civil Procedure 30(b)(6) and related document requests on the following topics: (1) Johnson & Johnson and Janssen's corporate structure; (2) their involvement in the development, manufacturing, sale, and promotion of Invokana; (3) contractual agreements among the Defendants; (4) studies and other clinical trials related to *canagliflozin*; and (5) scientific studies showing increased risks of *canagliflozin* and related communications with the FDA.

F. Alternately, Plaintiff Requests the Opportunity to Amend His Complaint.

Alternately, should this Court find Plaintiff's Complaint defective in any way, Plaintiff respectfully requests leave to amend. Under Rule 15(a)(2), leave to amend should be "freely" granted when "justice so requires." Although Plaintiff firmly believes his Complaint is sufficient

as is, should this Court determine otherwise, Plaintiff should be afforded the opportunity to reallege his claims in a manner acceptable to all parties and to this Court.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motion to dismiss.

Dated: March 11, 2016

Respectfully submitted,

/s/ Travis P. Lepicier

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 11th day of March, 2016, a copy of the foregoing was filed electronically with the Clerk of Court to be served via the Court's electronic case filing system on all counsel of record.

/s/ Travis P. Lepicier
Timothy M. O'Brien, Esq. (*Via Pro Hac Vice*)
Florida Bar No. 055565
Travis P. Lepicier, Esq. (*Via Pro Hac Vice*)
Florida Bar No.
LEVIN PAPANTONIO, ET AL.
316 S. Baylen Street, 6th Floor
Pensacola, FL 32502
850-435-7084
850-436-6084 (fax)
tobrien@levinlaw.com
tlepicier@levinlaw.com

Timothy R. Holton, Esq. (Bar # 11832)
HOLTON LAW FIRM
296 Washington Avenue
Memphis, TN 38103
tholton@holtonlaw.com

ATTORNEYS FOR PLAINTIFF